

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION**

IN RE MENTOR CORP. OBTAPE  
TRANSOBTURATOR SLING PRODUCTS  
LIABILITY LITIGATION

MDL CASE NO. 4:08-md-2004

Individual Case No. 09-cv-5041 (Torres-  
Jacobs)

**MENTOR CORPORATION'S ANSWER AND AFFIRMATIVE DEFENSES**

Defendant Mentor Corporation ("Mentor"), by and through its attorneys, hereby answers Plaintiffs Maria M. Torres-Jacobs' and David E. Jacob's ("Plaintiffs") Complaint as follows:

**JURISDICTION AND PARTIES**

1. In response to Paragraph 1 of the Complaint, upon information and belief, Mentor admits the allegations contained therein.

2. In response to the first sentence of Paragraph 2 of the Complaint, Mentor admits that it is a Minnesota corporation and its principal place of business is in California. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 2.

3. In response to Paragraph 3 of the Complaint, Mentor admits that Plaintiffs are purporting to seek damages in excess of \$75,000 and that subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation in Paragraph 3 of the Complaint.

4. In response to Paragraph 4 of the Complaint, based upon Plaintiffs' representations in the Complaint, Mentor admits that venue is proper in the District of Minnesota. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation in Paragraph 4 of the Complaint.

**FACTUAL BACKGROUND**

5. In response to Paragraph 5 of the Complaint, Mentor admits that Mentor was, at certain times, engaged in the business of designing, manufacturing, packaging, labeling, and selling medical devices. Mentor further admits that, at certain times, it distributed ObTape Transobturator Tape to physicians and that ObTape Transobturator Tape was indicated for the surgical treatment of stress urinary incontinence. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 5.

6. In response to Paragraph 6 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

7. In response to Paragraph 7 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

8. In response to Paragraph 8 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

9. In response to Paragraph 9 of the Complaint, Mentor admits that it distributed ObTape Transobturator Tape to physicians in the United States and that it stopped distributing ObTape Transobturator Tape around March 2006. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 9.

10. In response to Paragraph 10 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

11. In response to Paragraph 11 of the Complaint, Mentor is without information or knowledge sufficient to form a belief as to the truth of the allegations as stated therein and, on that basis, denies them.

12. In response to Paragraph 12 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

**COUNT I: STRICT LIABILITY - DEFECTIVE MANUFACTURE**

13. In response to Paragraph 13 of the Complaint, Mentor incorporates by reference the admissions, denials and averments of Paragraphs 1-12 of this Answer as if fully rewritten herein.

14. In response to Paragraph 14 of the Complaint, Mentor admits that it distributed ObTape Transobturator Tape to physicians. Except as specifically admitted, Mentor denies, generally and specifically, each and every remaining allegation of Paragraph 14.

15. In response to Paragraph 15 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

16. In response to Paragraph 16 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

17. In response to Paragraph 17 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

18. In response to Paragraph 18 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

19. In response to Paragraph 19 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

20. In response to Paragraph 20 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

21. In response to Paragraph 21 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

22. In response to Paragraph 22 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

23. In response to Paragraph 23 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

24. In response to Paragraph 24 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein..

**COUNT II: STRICT LIABILITY - DEFECTIVE DESIGN**

25. In response to Paragraph 25 of the Complaint, Mentor incorporates by reference the admissions, denials and averments of Paragraphs 1-24 of this Answer as if fully rewritten herein.

26. In response to Paragraph 26 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

27. In response to Paragraph 27 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

28. In response to Paragraph 28 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

29. In response to Paragraph 29 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

30. In response to Paragraph 30 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

31. In response to Paragraph 31 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

32. In response to Paragraph 32 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

33. In response to Paragraph 33 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

34. In response to Paragraph 34 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

**COUNT III: STRICT LIABILITY – FAILURE TO WARN OR INSTRUCT**

35. In response to Paragraph 35 of the Complaint, Mentor incorporates by reference the admissions, denials and averments of Paragraphs 1-34 of this Answer as if fully rewritten herein.

36. In response to Paragraph 36 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

37. In response to Paragraph 37 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

38. In response to Paragraph 38 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

39. In response to Paragraph 39 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

40. In response to Paragraph 40 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

**COUNT IV: NEGLIGENCE**

41. In response to Paragraph 41 of the Complaint, Mentor incorporates by reference the admissions, denials and averments of Paragraphs 1-40 of this Answer as if fully rewritten herein.

42. In response to Paragraph 42 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

43. In response to Paragraph 43 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

44. In response to Paragraph 44 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

45. In response to Paragraph 45 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

46. In response to Paragraph 46 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

**COUNT V: LOSS OF CONSORTIUM CLAIM ON BEHALF OF-  
PLAINTIFF DAVID E. JACOBS**

47. In response to Paragraph 47 of the Complaint, Mentor incorporates by reference the admissions, denials and averments of Paragraphs 1-46 of this Answer as if fully rewritten herein.

48. In response to Paragraph 48 of the Complaint, Mentor denies, generally and specifically, each and every allegation contained therein.

49. Mentor denies that Plaintiffs are entitled to any relief.

50. Mentor denies any allegation contained in the Complaint that is not expressly admitted by Mentor.

### **AFFIRMATIVE DEFENSES**

Mentor maintains that discovery and investigation may reveal that one or more of the following affirmative defenses should be available to Mentor in this matter. Mentor, therefore, asserts said defenses to preserve the right to assert them as separate and distinct affirmative defenses to the Complaint and to the causes of action therein. Upon completion of discovery, and if the facts warrant, Mentor may withdraw any of its defenses as may be appropriate. Further, Mentor reserves the right to amend this Answer to assert additional claims or defenses as discovery proceeds.

#### **FIRST AFFIRMATIVE DEFENSE**

##### **(Failure to State a Claim)**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

#### **SECOND AFFIRMATIVE DEFENSE**

##### **(Statute of Limitations and Laches)**

The claims against Mentor are barred by laches and/or the applicable statute of limitations.

#### **THIRD AFFIRMATIVE DEFENSE**

##### **(Waiver and Estoppel)**

The claims against Mentor are barred by waiver and/or estoppel.

#### **FOURTH AFFIRMATIVE DEFENSE**

##### **(Contributory Fault)**

If Plaintiffs sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused in whole or in part by Plaintiffs' own negligence and fault and were not caused or contributed to in any manner, by any alleged fault, negligence or

breach of warranty of Mentor, its officers, agents, contractors, servants, employees, or others for whom it was responsible. Plaintiffs' recovery should be diminished by that percentage of fault attributable to Plaintiffs and/or persons or entities other than Mentor for those injuries sustained by Plaintiffs upon which the damages complained of in this action are based. Thus, Mentor's liability, if any, is limited to its percentage of responsibility for the injuries of Plaintiffs, if any, regardless of whether or not other persons or entities are named as co-defendants.

#### **FIFTH AFFIRMATIVE DEFENSE**

##### **(Fault of Others)**

If Plaintiffs sustained damages as alleged in the Complaint, which is denied, said damages were caused solely by or contributed to by the acts and fault of third parties and were not caused or contributed to by any acts or fault of Mentor, its officers, agents, servants, employees, contractors, or others for whom it was responsible. Mentor will identify the other persons or entities that may have been responsible with as much particularity as is feasible as discovery progresses and in sufficient time to allow the Plaintiffs to respond and/or file pleadings. Thus, Plaintiffs' claims should be barred or proportionately reduced by the intentional and/or negligent acts of such known or unknown parties.

#### **SIXTH AFFIRMATIVE DEFENSE**

##### **(Mitigation of Damages)**

If Plaintiffs sustained damages as alleged in the Complaint, which is denied, Plaintiffs have failed to mitigate their damages and any recovery is to be diminished by the degree to said failure to mitigate.



### **SEVENTH AFFIRMATIVE DEFENSE**

#### **(Assumption of Risk)**

The allegations set forth in the Complaint are barred on the grounds that Plaintiffs knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the Complaint, if any, and nevertheless did expressly, freely, and voluntarily assume said risk, and this undertaking proximately caused and contributed to the losses, injuries, or damages, if any, alleged by Plaintiffs.

### **EIGHTH AFFIRMATIVE DEFENSE**

#### **(Assumption of Risk/Informed Consent)**

Upon information and belief, Plaintiffs had full knowledge of the risks and possible adverse effects pertaining to the procedures performed upon them and all or part of the alleged injuries, damages, and/or losses, if any, sustained by Plaintiffs arose from and were caused by risks of which Plaintiffs were aware, and such risks were accepted and assumed by them, and for that reason any recovery against Mentor should be diminished, reduced, offset, or barred in accordance with the principles of assumption of the risk and/or informed consent.

### **NINTH AFFIRMATIVE DEFENSE**

#### **(Collateral Sources)**

Mentor is entitled to a set-off from any recovery against it to the extent each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources.

### **TENTH AFFIRMATIVE DEFENSE**

#### **(Superior Knowledge of Plaintiffs' Physicians and Medical Care Providers)**

At all times relevant hereto, the knowledge of Plaintiffs' physicians and/or other medical care providers with respect to the possible risks of surgery and the opportunity to warn of the possible risks of surgery, was superior to that of Mentor, and, therefore, if there was any duty to warn Plaintiffs of the risks of surgery, it was the duty of said physicians and/or other medical care providers, not of Mentor, and breach of that duty was an intervening and/or superseding cause of the injuries alleged by Plaintiffs.

### **ELEVENTH AFFIRMATIVE DEFENSE**

#### **(Plaintiffs' Physicians/Medical Care Providers Were Sophisticated Users)**

Plaintiffs' physicians and/or medical care providers, including their agents, servants and employees, by reason of the warnings and handling information given to them and their own long-standing and continuous experience with the products or materials, if any, referred to in the Complaint, are and were sophisticated users of any and all such products or materials, and thereby acquired a separate and affirmative duty to warn Plaintiffs of any alleged potential harmful effects from the use or misuse of said products or materials. By reason of the foregoing, the failure of said physicians and/or medical care providers to discharge said duty directly and proximately caused any and all damages and injuries, if any, complained of by Plaintiffs.

### **TWELFTH AFFIRMATIVE DEFENSE**

#### **(Learned Intermediary)**

The device referred to in the Complaint is a medical device available only upon the prescription and/or order of a licensed physician and/or surgeon and is not available to the general public. Mentor provided information concerning warnings, precautions, and

complications to those persons to whom the medical devices were available. Thus, Plaintiffs' claims are barred, in whole or in part, by the "learned intermediary" doctrine.

### **THIRTEENTH AFFIRMATIVE DEFENSE**

#### **(Adequate Warnings)**

If it is proven at the time of trial that Plaintiffs came into contact with Mentor's product, which is denied, then any product manufactured and/or sold and/or distributed by Mentor which was or may have been furnished to Plaintiffs and which they came into contact or may have come into contact with, was furnished with adequate and appropriate warnings.

### **FOURTEENTH AFFIRMATIVE DEFENSE**

#### **(Alteration of Products)**

Plaintiffs' physicians and/or medical care providers may have modified, altered or changed the Mentor products, if any, referred to in the Complaint, so that such changes in any said products or materials proximately caused Plaintiffs' injuries, loss, and damages, if any.

### **FIFTEENTH AFFIRMATIVE DEFENSE**

#### **(Benefits Outweigh Risks)**

The benefits of Mentor products or materials, if any, referred to in the Complaint outweigh the risk of danger and/or harm, if any, inherent in said products or materials.

### **SIXTEENTH AFFIRMATIVE DEFENSE**

#### **(No Warranty)**

The Plaintiffs and/or their physicians and/or medical care providers did not receive, directly or indirectly, nor rely upon any express or implied warranty from Mentor, or, if so, any breach thereof by Mentor was not a proximate cause of Plaintiffs' injuries or damages as alleged in the Complaint.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

(Express Warranty Disclaimer)

Mentor expressly disclaimed any warranty of its product in its warnings provided to Plaintiffs' physicians and/or surgeon and/or medical care providers, and Plaintiffs and/or their physicians and/or surgeon and/or medical care providers were aware, or should have been aware, of Mentor's specific warranty disclaimer.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

(No Representation to the Public)

With respect to the medical device referred to in the Complaint, if any were manufactured by Mentor, no representations were made by Mentor to the public at large in order to induce purchase of said products or materials.

**NINETEENTH AFFIRMATIVE DEFENSE**

(Independent, Intervening, or Superseding Cause)

Plaintiffs' injuries, if any, were proximately caused by unforeseeable, independent, intervening and/or superseding event(s) beyond the control, and unrelated to any conduct, of Mentor. Mentor's actions or omissions, if any, were superseded by the negligence and wrongful conduct of others.

**TWENTIETH AFFIRMATIVE DEFENSE**

(Alternate Cause)

The injuries and damages of which Plaintiffs complain were not caused by any product distributed by Mentor, but were caused by some other product, process, occurrence, event, or service over which Mentor exercised no control or right of control.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

(Preemption of Federal Law)

Federal statutes and regulations preempt all state law governing the product that is the subject of the Complaint, and said product was in compliance with Federal law at all times relevant to this cause of action.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

(Restatement (Second) of Torts)

The claims against Mentor are barred, in whole or in part, by the provisions of Comments “j” and “k” to Section 402A of the Restatement (Second) of Torts.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

(State of the Art)

Any and all acts performed by, and products designed and manufactured and/or distributed by Mentor were at all times relevant to the Complaint in conformity with the state of the art for the design and manufacture of such similar devices, and thus Plaintiffs’ claims are barred.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

(State of the Art)

The actions of Mentor were in compliance with all existing safety standards and precautions then consistent with the state of the medical art and thus Plaintiffs’ claims are barred.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

(Open and Obvious)

Any dangers associated with the use of the medical devices that may have caused Plaintiffs' injuries, if any, were open and obvious, and Plaintiffs are therefore barred from recovery.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

(Idiosyncratic Reaction)

Some or all of the injuries alleged in the Complaint were caused or aggravated by Plaintiffs' pre-existing medical condition or exposure to other substances utilized throughout their lifetime, by Plaintiffs' unusual susceptibility to injury, or by their idiosyncratic reaction.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

(Conformity with Governmental Regulations)

Any and all warnings or information pertaining to products designed, manufactured and/or distributed and/or sold by Mentor were at all times relevant to the Complaint in conformity with governmental requirements.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

(UCC Defenses)

Mentor is entitled to the benefits of all defenses and presumptions contained in, or arising from, any Uniform Commercial Code provisions enacted by the State of Minnesota.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

(Unintended and Unforeseeable Misuse, Modification, or Abuse of the Product)

If any product manufactured, distributed or sold by Mentor caused harm as alleged, which is denied, then such harm was proximately caused by misuse, modification, and/or abuse of the product in a manner neither intended nor foreseen by Mentor.

**THIRTIETH AFFIRMATIVE DEFENSE**

(No Feasible Alternative Design)

Mentor states that there is no alternative design for the product that was capable of preventing Plaintiffs' injuries.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

(Preemption)

The conduct of Mentor and all activities with respect to the subject product have been and are under the supervision of the United States Food and Drug Administration. Accordingly, this action is barred by the doctrine of primary jurisdiction and preemption.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

(Accord and Satisfaction/Release)

Plaintiffs' claims are barred by the doctrine of accord and satisfaction and/or release.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

(Lack of Notice)

The claims for breach of warranty are barred due to the failure to provide Mentor requisite or timely notice of any claimed breach of warranty.

### **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

#### **(Punitive Damages Unconstitutional)**

Plaintiffs' claims for punitive damages are in contravention of Mentor's rights under each of the following constitutional provisions:

- a. the Commerce Clause of Article I, Section 8 of the United States Constitution;
- b. the Contracts Clause of Article I, Section 10 of the United States Constitution;
- c. the prohibition against ex post facto laws embodied in Article I, Section 10 of the United States Constitution;
- d. the Supremacy Clause of Article VI of the United States Constitution;
- e. the Free Speech Clause of the First Amendment of the United States Constitution;
- f. the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution;
- g. the Takings Clause of the Fifth Amendment of the United States Constitution
- h. the Right to Counsel of the Sixth Amendment of the United States Constitution;
- i. the Excessive Fines Clause of the Eighth Amendment of the United States Constitution;
- j. the Right to Trial by Jury contained in the Seventh Amendment of the United States Constitution;
- k. the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and
- l. similar or corresponding provisions of the Constitution of this State.



**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

(Punitive Damages Barred)

No act or omission of Mentor was malicious, willful, or reckless and, therefore, any award of punitive damages is barred.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

(Punitive Damages Barred)

With respect to Plaintiffs' demand for punitive damages, Mentor specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive damage awards that are set forth in *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and similar State cases.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

(Punitive Damages Barred)

Because of the lack of clear standards, any imposition of punitive damages against Mentor would be unconstitutionally vague and/or overbroad.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

(Lack of Privity)

Plaintiffs' claims are barred for lack of privity.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

(Notice of Additional Affirmative Defenses)

Mentor hereby gives notice that it intends to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and thus reserves the right to amend its Answer to assert such defenses.

WHEREFORE, Defendant Mentor Corporation prays as follows:

- (1) That Plaintiffs take nothing by virtue of the Complaint herein and that this action be dismissed in its entirety;
- (2) For costs of suit and attorneys' fees herein incurred; and
- (3) For such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Defendant Mentor Corporation demands a jury trial of all issues so triable.

Dated: August 19, 2009

Respectfully submitted,

s/ John Q. Lewis

John Q. Lewis

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Designated Lead Counsel for Defendant  
Mentor Corporation

**IN RE: MENTOR CORP. OBTAPE TRANSOBTURATOR  
SLING PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2004**

**CERTIFICATE OF SERVICE**

A copy of the foregoing filing was served via ECF and by electronic mail on the following counsel this 19th day of August 2009:

Henry Gilbert Garrard, III  
[hgg@bbgbalaw.com](mailto:hgg@bbgbalaw.com)  
Lead and Liaison Counsel for Plaintiffs

s/ John Q. Lewis  
Attorney for Defendant  
Mentor Corporation